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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,005	07/03/2003	Juergen Andrew Kortenbach	06530.0170-05	3367
22852	7590	04/16/2009	EXAMINER	
		FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER	YABUT, DIANE D	
		LLP		
		901 NEW YORK AVENUE, NW	ART UNIT	PAPER NUMBER
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			04/16/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/612,005	KORTENBACH, JUERGEN ANDREW	
Examiner	Art Unit		
DIANE YABUT	3734		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 13 January 2009.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 110,113-130 and 133-139 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) 113,114,129,130 and 133-139 is/are allowed.

6)  Claim(s) 110 and 115-128 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO/SB/08)  
    Paper No(s)/Mail Date . . .

4)  Interview Summary (PTO-413)  
    Paper No(s)/Mail Date. \_\_\_\_ .  
5)  Notice of Informal Patent Application  
6)  Other: \_\_\_\_ .

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/13/2009 has been entered.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims **110, 115-124 and 128** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bolanos** (U.S. Patent No. **5,897,562**).

Claims 110 and 115-116: Bolanos discloses an invagination device comprising an elongated tube having a proximal end and a distal end, a distal member coupled proximate the distal end of the tube and configured to fold a fundus of a stomach toward an esophageal wall, the distal member comprising a stationary member **92** having a proximal end coupled to the distal end of the tube and a distal end, a rotatable member

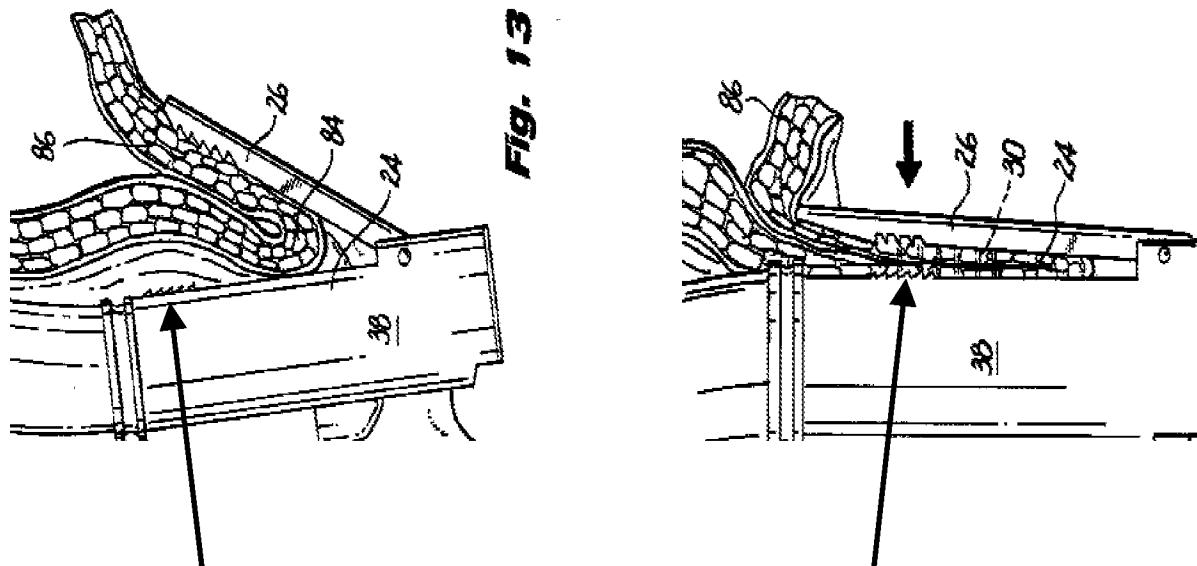
**104** pivotably coupled to the distal end of the stationary member and configured to install at least one fastener (in that it securely clamps tissue to aid in effectively positioning and firing the fasteners therethrough), the rotatable member having a connected end and a free end and being configured to pivot between a first position in which the free end is located distally of the connected end and a second position in which the connected end is located distally of the free end (Figures 19-23).

Bolanos discloses the rotatable member **104** having a connected end **110** connected to the distal end of the first member or stationary member **92** and a free end, and the second member being configured to pivot between a first position in which the free end is located distally of the connected end and a second position in which the connected end is located distally of the free end (Figures 21-22).

Bolanos discloses at least one of the first and second members being configured to install at least one fastener which is configured to fasten multiple tissue layers and the fastener has a first part and a second part, the first member being configured to hold the first part and the second member being configured to hold the second part in opposed relation with the first part (Figures 27-28)

Bolanos discloses a grasper (other member **104** in Figure 22), but does not disclose positioning the grasper between a first surface on the rotatable member and a second surface on the stationary member, wherein the first surface faces the second surface in the second position.

However, Bolanos does disclose a stapling device having a grasper or gripping surface (teeth) in between a rotatable member **26** and a stationary member **38** as indicated by the arrows in annotated Figures 13 and 14:



It would have been obvious to one of ordinary skill in the art at the time of invention to provide such a gripping or grasping surface between the rotatable member and stationary member, in order to facilitate grasping of tissue, and therefore facilitate folding and stapling the tissue.

Claims 117-120: Bolanos discloses a control member or actuator **112** located or coupled proximate the proximal end of the tube configured to control operation of at least one of the distal member and the grasper, the control member located proximate the proximal end of the tube and comprising at least one control cable extending from the control member to at least one of the distal member and the grasper through the tube, and the tube including a port for an endoscope **102** and wherein the grasper is

capable of grasping a gastroesophageal junction (Figures 19 to 21, col. 8, line 55 to col. 9 line 4).

Claims 121-124 and 128: Bolanos discloses a method of performing invagination, which comprises providing the surgical instrument of claim 110, inserting the surgical instrument transorally into a stomach, grasping a portion of the fundus or the esophageal wall with the grasper, and folding the fundus toward the esophageal wall with the distal member, while grasping the portion of the fundus or the esophageal wall, and the grasper being integrally formed with the distal member, the distal member including a stationary member, the rotatable member being pivotably coupled to the stationary member, and the step of folding the fundus including rotating the rotatable member with respect to the stationary member so as to fold the fundus toward the esophageal wall and applying at least one fastener to secure the fundus to the esophageal wall (Figures 19-28; col. 3, lines 10-21, col. 9, lines 34-65).

4. Claims **125-127** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bolanos** (U.S. Patent No. **5,897,562**) in view of **Harrison** (U.S. Patent No. **5,403,326**).

Claims 125-127: Bolanos discloses the claimed device, including actuating an actuator **112** located or coupled proximate the proximate end of the tube configured to control operation of at least one of the distal member and the grasper (Figures 19 to 21, col. 8, line 55 to col. 9 line 4), except for an actuator being used for engagement between male and female members of a fastener.

Harrison teaches an actuator **72** being used for engagement between male and female members of a fastener (col. 8, lines 1-10). It would have been obvious to one of ordinary skill in the art at the time of invention to provide an actuator control member being used for engagement between male and female members of a fastener, as taught by Harrison, to Bolanos since it was known in the art that male and female, or two-part fastener members, are common in the art as well as providing secure engagement with tissue to prevent undesirable movement.

Bolanos also discloses the claimed device except for a fastener having a male member and a female member, and the rotatable member being configured to hold one of the male member and female members, the distal member further comprising a stationary member coupled to the rotatable member and configured to hold another of the male and female members in opposed relation with the one of the male and female members, and rotating the rotatable member with respect to the stationary member so as to cause engagement between the male and female members.

Harrison teaches a fastener having a male member **92,94** and a female member **96**, and the rotatable member being configured to hold one of the male member and female members, the distal member further comprising a stationary member coupled to the rotatable member and configured to hold another of the male and female members in opposed relation with the one of the male and female members, and rotating the rotatable member with respect to the stationary member so as to cause engagement between the male and female members (Figure 8C-8D).

It is noted that one of the male member and female members is considered stationary once it grasps the tissue and another of the male and female members can rotate towards the stationary member (angular displacement). It would have been obvious to one of ordinary skill in the art at the time of invention to provide the male and female members, as taught by Harrison, to Bolanos since it was known in the art that male and female, or two-part fastener members, are common in the art to provide secure engagement with tissue to prevent undesirable movement, and that rotation in the process of applying fastener members facilitates the device maneuvering around tissue and layers of tissue.

***Allowable Subject Matter***

5. Claims 113-114 and 129-130, 133-139 are allowed.

6. The following is an examiner's statement of reasons for allowance:

None of the prior art of record, alone or in combination discloses a grasper that is rotatably or pivotably coupled to a stationary member while also being positioned in between a first surface defined by the stationary member, and a second surface defined by a rotatable member that is pivotally coupled to the stationary member.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Response to Arguments***

7. Applicant's arguments with respect to claims 110 and 115-128 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/  
Examiner, Art Unit 3734

/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3734